23233. Adulteration and misbranding of tincture of digitalis, syrup of iron iodine, and fluidextract of ergot. U. S. v. Brewer & Co., Inc. Plea of nolo contendere. Fine, $55. (F. & D. no. 31335. Sample nos. 10698–A, 34447–A, 34448–A.)

This case was based on shipments of tincture of digitalis and fluidextract of ergot, which when tested by the methods prescribed in the United States Pharmacopoeia, had a potency much lower than provided therein; and a shipment of syrup of iron iodine that contained less ferrous iodide than provided in the pharmacopoeia. The fluidextract of ergot, when used as directed on the label, would not produce the therapeutic effects claimed.

On June 1, 1934, the United States attorney for the District of Massachusetts, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Brewer & Co., Inc., a corporation, Worcester, Mass., alleging shipment by said company, in violation of the Food and Drugs Act as amended, on or about March 3, 1932, from the State of Massachusetts into the State of Pennsylvania of a quantity of syrup iron iodine, and on or about February 20, 1933, from the State of Massachusetts into the State of Maine of quantities of tincture digitalis and fluidextract ergot, which were adulterated and misbranded. The articles were labeled in part: "Tincture Digitalis U. S. P. X."; "Syrup Iron Iodine U. S. P. Syrup of Ferrous Iodide"; "Fluidextract Ergot (Fluidextractum Ergotae U. S. P.) * * * Emmenagogue, Oxytocic, Hemostatic Circulatory Equalizer"; "Brewer & Company, Inc. Pharmaceutical Chemists, Worcester, Mass."

The information charged that the tincture digitalis and syrup iron iodine were adulterated in that they were sold under and by names recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia official at the time of investigation, in the following respects, and their own standard of strength, quality, and purity were not declared on the containers.

The tincture digitalis when injected into the ventral lymph sac of a frog had a minimum systolic dose of less than 0.0055 cubic centimeter, equivalent to less than 0.00,000,046 gram of ouabain for each gram of body weight of frog, whereas the pharmacopoeia provides that tincture of digitalis, when injected into the ventral lymph sac of a frog shall have a minimum systolic dose of not less than 0.0055 cubic centimeter, equivalent to not less than 0.00,000,046 gram of ouabain for each gram of body weight of frog.

The syrup iron iodine (syrup of ferrous iodide) contained less than 6.5 grams, namely, not more than 5.2 grams of ferrous iodide per 100 cubic centimeters, whereas the pharmacopoeia provides that syrup of ferrous iodide shall contain not less than 6.5 grams of ferrous iodide per 100 cubic centimeters. Adulteration of the fluidextract ergot was alleged in that it was sold under and by a name recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia, and the standard of strength, quality, and purity of the article was not declared on the container thereof. Adulteration was alleged for the further reason that the strength, quality, and purity of the articles fell below the professed standard and quality under which they were sold, in that they were represented to be products which conformed to the standard laid down in the United States Pharmacopoeia; whereas they were not.

Misbranding was alleged for the reason that the statements, "Tincture Digitalis U. S. P. X.", "Syrup Iron Iodide U. S. P., Syrup of Ferrous Iodide", and "Fluidextract Ergot (Fluidextractus Ergotae U. S. P.)" borne on the labels of the respective products, were false and misleading. Misbranding of the fluidextract ergot was alleged for the further reason that certain statements on the bottle label falsely and fraudulently represented that it was effective as an emmenagogue, oxytocic, and hemostatic circulatory equalizer, when taken as directed; whereas it was not effective as an emmenagogue, oxytocic, or hemostatic circulatory equalizer when taken as directed.

On October 5, 1934, a plea of nolo contendere was entered on behalf of the defendant company, and the court imposed a fine of $55.

M. L. WILSON, *Acting Secretary of Agriculture.*